REMARKS

Claims 1-13 are pending in the application. Claims 11-13 are currently amended. Claims 1-10 are original. A copy of the claims now pending in the application showing changes made to currently amended claims in accord with 37 C.F.R. § 1.121, as revised, has been provided.

No new matter has been introduced by virtue of the amendments made herein. Accordingly, Applicant respectfully requests their entry. In view of the amendments made herein and the remarks below, Applicant respectfully requests reconsideration and withdrawal of rejections set forth in the August 10, 2004 Office Action.

Rejection under 35 USC § 112, second paragraph

Claims 11-13 were rejected under 35 USC § 112, second paragraph by the Examiner for allegedly failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the Examiner has claims 11-13 recite a use without any active, positive steps delimiting how this use is actually practiced.

Without prejudice, and in the interest of facilitating prosecution, Applicant has amended claims 11-13 into method claims, setting forth positive steps delimiting how the use of these claims is actually practiced.

In view of the above amendments, Applicant submits that currently amended claims 11-13 are all patentable under 35 U.S.C. 112, second paragraph, and respectfully requests withdrawal of the rejection and allowance of these claims.

Rejection under 35 USC § 101

Claims 11-13 were rejected under 35 USC § 101, by the Examiner for allegedly reciting a use without setting forth any steps involved in the process.

As stated above, Applicant has amended claims 11-13 into method claims, setting forth positive steps delimiting how the use of these claims is actually practiced.

In view of the above amendments, Applicant submits that currently amended claims 11-13 are all patentable under 35 U.S.C. 101, and respectfully requests withdrawal of the rejection and allowance of these claims.

Rejection under 35 USC § 103(a)

Claims 1-13 were rejected under 35 USC § 103(a) for allegedly being unpatentable over Doogan et al. (U.S. 4,962,128) in view of Howard et al. (U.S. 5,597,826) and Johnson (EP0768083). Applicant respectfully traverses this rejection.

Doogan et al. discloses pharmaceutical compositions for oral administration which are aqueous. Specifically, Doogan et al. disclose that when aqueous suspensions and/or elixirs are desired for oral administration, the sertraline, or its pharmaceutically acceptable salt, may be combined with diluents such as water, ethanol, propylene glycol, glycerin, and combinations thereof. See col. 2, line 63 to col. 3, line 2.

In contrast, the presently claimed invention discloses an essentially nonaqueous, liquid concentrate for oral administration comprising an amount of sertraline or a pharmaceutically acceptable salt thereof and one or more essentially nonaqueous pharmaceutically acceptable excipients, wherein at least one of the excipients is liquid. Doogan et al. do not suggest or disclose an essentially nonaqueous, liquid concentrate for oral administration comprising an amount of sertraline or a pharmaceutically acceptable salt thereof and one or more essentially nonaqueous pharmaceutically acceptable excipients, wherein at least one of the excipients is liquid. Furthermore, Doogan et al. do not motivate one skilled in the art to modify the teaching of Doogan et al. in order to arrive at an essentially nonaqueous, liquid concentrate for oral administration comprising an amount of sertraline or a pharmaceutically acceptable salt thereof and one or more essentially nonaqueous pharmaceutically acceptable excipients, wherein at least one of the excipients is liquid. Accordingly, Doogan et al. do not render the claimed invention obvious.

Howard et al. do not correct the deficiencies of Doogan et al. Howard et al. describes setraline containing pharmaceutical compositions for oral administration in col. 22, lines 37-57. However, Howard et al. do not suggest or disclose an essentially nonaqueous, liquid concentrate for oral administration comprising an amount of sertraline or a pharmaceutically acceptable salt thereof and one or more essentially nonaqueous pharmaceutically acceptable excipients, wherein at least one of the excipients is liquid. Furthermore, Howard et al. do not motivate one skilled in the art to modify the teachings of Doogan et al. in order to arrive at an essentially nonaqueous, liquid concentrate for oral administration comprising an amount of sertraline or a pharmaceutically acceptable salt thereof and one or more essentially nonaqueous pharmaceutically acceptable excipients, wherein at least one of the excipients is liquid. Accordingly, Howard et al. do not render the claimed invention obvious.

Johnson does not correct the deficiencies of Doogan et al. Just as disclosed in Doogan et al., Johnson discloses pharmaceutical compositions for oral administration which are aqueous. Specifically, Johnson discloses that when aqueous suspensions and/or elixirs are desired for oral administration, sertraline, or its pharmaceutically acceptable salt, may be combined with diluents such as water, ethanol, propylene glycol, glycerin, and combinations thereof. See page 3, lines 21-24.

In contrast, the presently claimed invention discloses an essentially nonaqueous, liquid concentrate for oral administration comprising an amount of sertraline or a pharmaceutically acceptable salt thereof and one or more essentially nonaqueous pharmaceutically acceptable excipients, wherein at least one of the excipients is liquid. Johnson does not suggest all disclose an essentially nonaqueous, liquid concentrate for oral administration comprising an amount of sertraline or a pharmaceutically acceptable salt thereof and one or more essentially nonaqueous pharmaceutically acceptable excipients; wherein at least one of the excipients is liquid. Furthermore, Johnson does not motivate one skilled in the art to modify the teachings of Doogan et al. or Howard et al. in order to arrive at an essentially nonaqueous, liquid concentrate for oral administration comprising an amount of sertraline or a pharmaceutically acceptable salt thereof and one or more essentially nonaqueous pharmaceutically

acceptable excipients, wherein at least one of the excipients is liquid. Accordingly, Johnson does not render the claimed invention obvious.

Because none of the references cited by the Examiner, either alone or in combination, provide the motivation necessary to arrive at the presently claimed invention for the reasons stated above, the Examiner has not established a *prima facie* case of obviousness. Furthermore, for the reasons stated above, none of the references cited by the Examiner, either alone or in combination, suggest or disclose the presently claimed invention. Accordingly, Applicant respectfully submits that claims 1-13 are all patentable under 35 U.S.C. 103(a), and respectfully requests withdrawal of the rejection and allowance of these claims.

Double Patenting Rejection

Claims 1-13 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-7 and 13 of U.S. Patent No. 6,727,283.

In the interest of facilitating prosecution, Applicant respectfully submit a timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(c). Accordingly, Applicant submits that this double patenting rejection is overcome, and respectfully request withdrawal of the rejection and allowance of these claims.

In view of the amendments set forth herein and the remarks above, Applicant respectfully submits that the pending claims are fully allowable, and solicit the issuance of a notice to such effect. If a telephone interview is deemed to be helpful to expedite prosecution of the subject application, the Examiner is invited to contact applicants' undersigned attorney at the telephone number provided.

The Commisioner is hereby authorized to charge any fees required under 37 C.F.R. §§1.16 and §1.17 or to credit any overpayment to Deposit Account No. 16-1445.

Date: Aug 27, 2004

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